# Quality of Care in Integrated Community Case Management Services in Bugoye, Uganda: a Retrospective Observational Study

## Abstract:

Background: Village health workers (VHWs) in 5 villages in Bugoye subcounty (Kasese District, Uganda) provide integrated community case management (iCCM) services, in which VHWs evaluate and treat malaria, pneumonia, and diarrhea in children under 5 years of age. VHWs use a "Sick Child Job Aid" that guides them through the evaluation and treatment of these illnesses. Malaria is diagnosed by rapid diagnostic test, pneumonia by age-based respiratory rate cutoffs, and diarrhea by symptoms as described by the caregiver.

Objectives: Measure the quality of iCCM services over time using routinely collected iCCM program data.

Methods: We used existing aggregate program data to: 1) summarize the patient population and services provided, and 2) measure quality of care based on concordance between matching categories or actions in the treatment algorithm. We then employed lot quality assurance sampling to create a patient-level dataset, and created a secondary patient-level dataset of all patients with "danger signs" (evidence of severe illness). Using patient-level records, we: 1) describe adherence to the iCCM algorithm; 2) measure VHW-level quality using lot quality assurance sampling decision rules; 3) assess change over time in quality of care with generalized estimating equations regression modeling.

Results: Most VHWs achieved greater than 90% concordance for all measures apart from concordance between number of patients presenting with fever and number of rapid diagnostic tests performed. From the main patient-level dataset, 97% (150) of patients with diarrhea were treated with oral rehydration and zinc, 95% (216) of patients with presumed pneumonia were treated with amoxicillin, and 94% (240) of patients with malaria were treated with artemisin combination therapy or rectal artesunate. However, only 44% (44) of patients with a negative rapid test for malaria were appropriately referred. Of patients with danger signs, 95% were appropriately referred to a health facility. Overall, 75% (434) of patients received all the correct evaluation and management steps. At the VHW level, 9 out of 23 VHWs have provided high-quality care over 2 years, based on the selected lot quality assurance sampling decision threshold (21 out of 25 patients with correct management). Quality of care increased

significantly in the first 6 months after initiation of iCCM services (p = 0.003), and then plateaued in months 7-24.

Conclusions: Quality of care was high for uncomplicated malaria, pneumonia and diarrhea. Overall quality of care was lower, partly because VHWs often did not follow the guidelines to refer patients who tested negative for malaria. Quality of care appears to improve as VHWs gain initial experience in iCCM care. Despite some limitations, lot quality assurance sampling and concordance are feasible and scalable approaches to measuring quality of iCCM care.

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# List of abbreviations

| | |
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| ACT | Artemisin combination therapy (for malaria) |
| CHW | Community health worker |
| GEE | Generalized estimating equation |
| iCCM | Integrated community case management |
| LQAS | Lot quality assurance sampling |
| ORS | Oral rehydration salts (for diarrhea) |
| QIC | Quasi-likelihood under the independence model criterion |
| RDT | Rapid diagnostic test (for malaria) |
| VHW | Village health worker |

# Introduction

## A. Program description

Village health worker (VHW) programs undertake a wide range of different activities in different settings, with varying levels of focus on health promotion, case finding, adherence support, clinical care, and other goals. In many programs, VHWs provide health education as well as initial assessment and referral to a health facility, but are not trained to administer medical treatment. However, in the last 10 years, interest has increased in equipping VHWs to provide assessment and curative treatment for young children, using different variants of Integrated Community Case Management (iCCM). In iCCM programs, VHWs (or other lay health workers without formal clinical training) provide diagnosis and treatment of malaria, pneumonia, and sometimes diarrhea in children under 5 years of age, using written protocols developed by the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), and other partners.

In Uganda, malaria is the leading cause of child mortality, causing almost one third of deaths (32%). Pneumonia is fourth-highest at 8% of deaths, while diarrheal disease causes 4% of child deaths (1).[1] Thus, these three diseases account for nearly half of under-five mortality in Uganda. Furthermore, children with these conditions can experience relatively acute deterioration in their condition, progressing rapidly from an illness manageable with a simple outpatient therapy to a complicated illness requiring inpatient hospital treatment, making prompt treatment essential. By decreasing barriers to care, iCCM has the potential to find and treat these children sooner, thereby decreasing morbidity and mortality. Recent studies in Uganda and Rwanda have demonstrated substantial decreases in child mortality after implementation of iCCM care – a 53% decrease in the smaller Ugandan study, and a 38% decrease after the Rwandan national iCCM rollout (2,3). Both studies employ an uncontrolled,

[1] The second-leading cause of death in children under five is perinatal/neonatal conditions (18% of deaths), while meningitis is third (10% of deaths). In the iCCM system, VHWs do not have a role in the treatment of meningitis; however, because they assess for non-specific "danger signs" such as seizures and altered level of consciousness, this system may allow them to detect and refer children with meningitis for prompt treatment.

before-after design; however, they are broadly consistent with each other, and provide an indication that iCCM care likely decreases child mortality.

While the Ugandan Ministry of Health endorses iCCM and sets forth guidelines on its implementation, iCCM has not yet been widely implemented in Uganda. The Massachusetts General Hospital Center for Global Health and Mbarara University of Science and Technology collaborate to support and evaluate a VHW program in Bugoye, Uganda, a rural area along the Uganda-Democratic Republic of Congo border. These VHWs are all volunteers, and most make a living as farmers. As a result, they have limited formal education, though all are literate in the local language of Lukonjo. In addition to health promotion efforts in their villages, these VHWs also provide iCCM services for malaria, pneumonia, and diarrhea in children under 5 years of age. This pilot project seeks to provide guidance to the Ministry of Health on the optimal implementation of iCCM on a wider scale.

In this program, VHWs provide protocol-based evaluation and treatment of these conditions using a paper-based "Sick Child Job Aid" (Figure 1), in keeping with iCCM guidelines. They are equipped with rapid diagnostic tests (RDT) for malaria diagnosis; pneumonia is diagnosed based on age-based respiratory rate cutoffs, and diarrhea is diagnosed by clinical history. For patients with "danger signs," VHWs provide initial assessment and referral or accompaniment to a health facility, as well as pre-referral treatment for some conditions.[2]

The VHWs in Bugoye received 3 brief training initial modules to equip them for their role. First, they received a 3-day training course on health promotion in their villages. Second, they received a 5-day training on provision of iCCM care. Third, they received a 2-day training on completing the iCCM forms. Additionally, they receive quarterly, one-day refresher trainings. VHWs also receive supervision visits from health workers at Bugoye Health Center, though

[2] In the Ugandan iCCM guidelines, the following signs and symptoms are considered danger signs: inability to breastfeed or drink, inability to maintain hydration orally because of constant vomiting, seizures, altered level of consciousness, cough for more than 21 days, diarrhea for more than 14 days, bloody diarrhea, fever for more than 7 days, a newborn with many skin pustules, or a newborn with an infected umbilical cord.

clinical duties sometimes make it difficult for the health workers to complete these supervisory visits. In keeping with the Ministry of Health guidelines for iCCM, VHWs use a "Sick Patient Register" to record all the patients they care for over the course of each month (Figure 2). At the end of each month, they submit the completed register at Bugoye Health Center. Program staff then tally the patients seen by each VHW, create a "Monthly Report" for the overall program, and file the Sick Patient Registers at Bugoye Health Center. The filed registers and monthly reports provided the 2 data sources for this research.

In addition to its potential benefits, iCCM also carries important risks of harm. Empowering VHWs to provide antimalarials and antibiotics could result in both overtreatment and undertreatment. Due to misunderstanding of treatment algorithms, a sense of personal responsibility, or community pressure, VHWs may overprescribe, increasing the risk of resistant organisms and exposing children with viral illnesses to the risks of medication without any benefit. Undertreatment also poses substantial risks. For instance, for pneumonia, if VHWs underestimate respiratory rates or fail to recognize other signs of respiratory distress, they may fail to treat or refer children with clinically significant bacterial infection. Parents or guardians, reassured by the VHW's assessment, may then fail to seek care elsewhere, increasing the risk of morbidity and mortality. Thus, measuring and improving quality of care represents an important issue for all iCCM programs. This thesis reports on a retrospective observational study to measure the quality of iCCM care provided by 23 VHWs in 5 villages in Bugoye subcounty over a 2-year period.

## B. Background on Integrated Community Case Management quality of care

We conducted a semi-systematic search for articles pertaining to quality of care in community case management. The overview below includes articles that focus on community case management of a single disease (e.g., malaria only or pneumonia only). However, it does not include articles on what is often called home-based management of fever, in which the only clinical intervention provided by VHWs is presumptive treatment for malaria in children with fever. While adherence to care protocols is important in such programs, the measurement of

quality is not comparable to that of iCCM, given the relative simplicity of the home-based fever management protocol. In addition, there is a separate literature on the impact of iCCM on health systems (e.g., its effect on utilization levels at health facilities), and on the impact of iCCM on child mortality; while important, these issues do not pertain directly to the study described here, and are not reviewed below.

We identified 3 relevant and recent systematic reviews, one focused on community case management of malaria (4), one focused mainly on malaria but that also reviewed programs providing malaria and pneumonia care (5), and the third on community case management of pneumonia (6). We did not find any prior systematic reviews of diarrhea management or iCCM specifically. Many of the articles reviewed here use the term "community health worker" (CHW) rather than the "village health worker" (VHW) term used in the Bugoye program, so we have preserved the CHW term in literature review below.

The first review that focused on malaria care documented very high quality of care by CHWs, with 95-100% correct interpretation of RDTs, and appropriate treatment of patients with positive RDTs in over 90% of cases (4). There was greater variation in rates of patients with negative RDTs inappropriately receiving treatment, ranging from 0.2% to 58% in the studies reviewed, though most studies showed rates of inappropriate treatment of less than 10%. Adherence to referral guidelines was much lower, with only 18.2% to 47.1% of patients receiving appropriate referral (4).

The second systematic review also documented very high quality of care by CHWs; the median proportion of RDT-positive patients receiving appropriate treatment with artemisin combination therapy (ACT) was 97.7%, while a median of 8.4% of RDT-negative patients were inappropriately treated with ACT (5). In 9 programs in which VHWs managed both malaria and pneumonia, they found a lower quality of care for pneumonia, with a median of 75.8% of patients diagnosed with pneumonia who received appropriate antibiotic treatment. Among studies that used reexamination by a clinician to assess quality, a median of only 63.7% of

pneumonia diagnoses made by CHWs matched with the clinician's diagnosis. Finally, they identified substantial variation (29.4% to 70%) in the proportion of patients with severe illness who were appropriately referred (5).

The third systemic review focused solely on pneumonia care (6). Overall, the quality of care for pneumonia patients cared for by CHWs was lower than that for malaria. In studies that used re-examination by a clinician, CHWs' assessments of normal versus fast breathing agreed with clinician assessments in 79% to 84% of cases. Of patients classified as having uncomplicated pneumonia by CHWs, about 80% received appropriate antibiotic treatment. There was a greater range between evaluations described in this review for rates of inappropriate treatment and adherence to referral guidelines. Rates of inappropriate treatment with antibiotics for patients who did not meet criteria for pneumonia ranged from 2% to 23%. Adherence to referral guidelines for severe illness ranged from 11% to 88% (6).

We also identified a large set of individual studies, assessing a variety of programs using variations of community case management. The remainder of this review will focus specifically on quality of care for iCCM – programs providing care jointly for malaria and pneumonia, with or without the inclusion of diarrhea care. Within these studies, there are two important distinctions worth bearing in mind. First, different programs and different countries have implemented iCCM using a range of workforce cadres, which are often lumped together as CHWs. However, these community health workers can range from part-time volunteers with a few weeks of training (often with limited formal education), to salaried government workers who have completed secondary school and up to a year of community health training. Some programs have also implemented iCCM using community health nurses to provide care. Unfortunately, some reports do not fully describe the characteristics of the CHWs providing care, which complicates interpretation of the results. Second, an important distinction lies in the methods used to assess quality of care. A subset of studies uses CHWs' clinical records to measure the quality of care provided. These studies have the advantage of being able to include large numbers of patient encounters. However, they cannot assess all aspects of quality

of care (e.g., correct determination of respiratory rate), and in a sense measure quality of the care documented, rather than quality of the actual care delivered. Another subset of studies employs direct observation of CHWs' patient encounters, often combined with re-examination of the patient by a trained clinician. These evaluations are able to measure a fuller scope of quality care, since they can assess clinical skills such as measuring respiratory rate or performing and interpreting an RDT. However, given the effort and cost required to employ direct observation and examination, these studies usually include fewer patient encounters; in addition, they place CHWs in an unfamiliar and stressful environment that may alter their performance. There are also several studies that employ multiple methods of measuring quality, with the goal of comparing these different methods.

Two recent studies of programs in which CHWs managed both malaria and pneumonia used record reviews to assess quality of care. One focused on CHWs in rural Zambia and found very high quality of care, with 94-100% of patients classified appropriately based on RDT and respiratory rate results (7). In this study, 94-100% of patients received appropriate treatment as well. The second study was a multi-site evaluation in Burkina Faso, Ghana, and Uganda (8). In this study, the CHWs in Burkina Faso and Uganda were laypeople, whereas in Ghana they were community health nurses. This study also showed substantial variation in performance between the 3 countries – for appropriate treatment of patients with positive RDTs, rates varied from 60% in Ghana to 99% in Uganda. Appropriate treatment of pneumonia was high throughout, with all sites having greater than 90% appropriate treatment. Inappropriate use of antimalarials was uncommon at all sites, with fewer than 5% of patients with a negative RDT receiving treatment. However, there was substantial variation in inappropriate antibiotic use for patients not meeting criteria for pneumonia, ranging from 0.9% in Uganda to 44.6% in Ghana (8).

Another recent study employed record review to assess iCCM care provided by drug shop owners rather than CHWs in Uganda (9). They demonstrated relatively high quality care for all three diseases, with appropriate treatment provided for 93.4% of patients with positive RDT,

91% for fast breathing, and 88.6% for diarrhea. In addition, 81.1% of patients with signs of severe illness were appropriately referred (9).

In regard to studies using direct observation, with or without reexamination of patients, there were 2 recent evaluations of part-time CHW programs in Uganda. In addition, there were 4 evaluations of programs that used full-time, salaried CHWs (2 in Malawi and 2 in Ethiopia). One study in Uganda used a mix of knowledge assessment, record review and direct observation; in the record review portion, they found high rates of appropriate treatment for malaria (99%) but somewhat lower rates of appropriate treatment for fast breathing (82%) (10). In the direct observation portion, 75% of CHWs were able to correctly classify patients with tachypnea or normal respiratory rate (10). The other evaluation in Uganda solely used direct observation; they similarly found high rates of appropriate treatment for children with positive RDT (95%), much lower rates of appropriate treatment for patients meeting criteria for fast breathing alone (40%), and high rates of appropriate treatment for children with a positive RDT and fast breathing (91%) (11).

One of the studies in Malawi, using salaried, full-time CHWs, explicitly compared different methods of assessing quality of care, including direct observation, record review, case scenarios, and direct observation with reexamination (the gold standard) (12). They found that for uncomplicated fever, there were similar results among all methods, and for uncomplicated diarrhea, record review actually underestimated quality of care compared to the other methods (including direct observation with reexamination). However, for uncomplicated fast breathing and for patients with danger signs, all other methods substantially overestimated quality of care compared to direct observation with reexamination. Overall, this study found higher quality of care for uncomplicated fever (87%) and diarrhea (90%), and lower quality for fast breathing (63%) and danger signs (24-40% depending on the presenting condition) (12). The other study in Malawi mirrored this trend, though showed lower quality overall, with rates of correct treatment of 79% for uncomplicated fever, 69% for diarrhea, and 52% for fast breathing (all by direct observation with reexamination) (13). In these studies RDTs were not

used, so the relative simplicity of the fever algorithm may account for this gradation in quality of care. In addition, because the direct observation approach is labor-intensive, these studies rely on relatively small subgroup sample sizes.

In Ethiopia, a recent evaluation using direct observation with reexamination in a low-malaria region, with salaried CHWs who had received substantial training, found similar quality of care for pneumonia (72% correct) and diarrhea (79% correct); there were insufficient malaria cases to draw meaningful conclusions (14). Another recent evaluation in Ethiopia compared direct observation with reexamination to record review, and found that record review, while broadly accurate, may overestimate quality by 13-14% (15).

Finally, there were several studies that employed direct observation to assess specific clinical skills only – CHWs' ability to perform an RDT and measure respiratory rates appropriately. While these are less relevant to the current study, they bear mention because these elements of quality of care cannot be measured using record review. A recent study in Zambia measured RDT performance over time, and found that CHWs' ability to administer the test correctly rose from 87.5% at 3 months to 100% at 6 months and 12 months, while correct interpretation of RDTs increased from 95.1% at 3 months to 98.3% at 6 months and 12 months (16). An evaluation of respiratory rate measurement in Uganda found that 79% of patients were classified correctly as normal respiratory rate or tachypnea; errors were relatively evenly split between incorrect counting of respiratory rate and misunderstanding of classification system (17).

In sum, there is strong evidence for CHWs' ability to provide high-quality care for uncomplicated malaria, both in single-disease models and iCCM models (which also incorporate pneumonia treatment, and in some cases, diarrhea treatment). Quality of care for pneumonia has been lower in prior studies, due to difficulty in measuring respiratory rate and difficulty with the iCCM algorithm for pneumonia, though some programs have demonstrated high-quality care. Evidence on quality of care for diarrhea is more limited, but shows relatively high

quality. Appropriate referral of patients with danger signs has generally been weak. While record review has its limitations, especially in regard to measuring clinical skills, it appears to be a reasonably accurate surrogate for quality of care.

There are several reasons for further evaluation of this topic. First, to bridge the gap between research-focused programs and widespread implementation, an approach to measuring quality that requires limited time input by staff, particularly clinical staff, is required. Even some prior record review studies, while not requiring substantial effort by clinical staff, entailed data entry of thousands of patient records. The approach demonstrated here, using a combination of pre-existing aggregate data and limited sampling of individual records (using a lot quality assurance sampling approach), helps minimize the cost of quality assurance efforts and diversion of staff time from implementation. Lot quality assurance sampling is intended to provide repeated assessments of approximate quality for naturally stratified data, and thus is highly appropriate for measuring iCCM quality of care. This approach could be used as a scalable tool for quality improvement. Second, apart from one study that examined only competence in performing RDTs (16), prior studies have not assessed VHWs over time to measure how their skills change – does competence increase with greater experience, or decrease as they get further away from their initial iCCM training? This study demonstrates a streamlined approach to quality measurement using aggregate data and lot quality assurance sampling, and also assesses how VHWs' performance evolves over time.

## Methods

This research study used 3 approaches to measure quality of VHW-delivered care over a 2-year period from March 2013 to February 2015. First, we used aggregate records summarizing all patient encounters for VHWs over 2 years (the program's "Monthly Reports") to summarize the care provided by VHWs and to assess concordance. Second, we sampled records from individual patient encounters recorded in the Sick Patient Registers to measure VHWs' adherence to iCCM protocols. We examined multiple metrics of quality of care at the program

level, and also assessed VHW-level quality using a lot quality assurance sampling (LQAS) approach. LQAS is an approach designed for naturally stratified data, in which it is desirable to make a binary determination of stratum quality (high or low quality) using relatively small sample sizes; the relevant section below provides further explanation. This patient-level dataset was also used to assess the primary analytic outcome, change in performance of VHWs over time. Third, we created a supplemental database of all patients recorded as having "danger signs" (e.g., seizures or altered level of consciousness) as well as all patients recorded as treated with rectal artesunate (to capture all patients who have been treated with this medication for severe malaria, even if they did not meet guidelines for its use). All analysis was conducted in Stata Version 12 (Statacorp, College Station, TX).

## A. Aggregate iCCM service delivery data

We collected the existing aggregate monthly reports in Microsoft Excel format, and combined them into a single database. Given the use of existing data which had been previously tallied and entered, we were limited in our ability to undertake data validation and cleaning. However, we completed limited data cleaning by identifying missing values and outliers, and comparing these fields to paper records, with correction of the database as appropriate. We then summarized all patient encounters from this program over 2 years, and assessed for concordance between matching categories or actions in the iCCM algorithm.

We used the following measures of concordance: 1) patients presenting with fever and patients receiving an RDT for malaria; 2) positive RDTs (i.e., malaria diagnoses) and malaria treatments prescribed; 3) patients presenting with diarrhea and ORS treatments prescribed; 4) patients presenting with diarrhea and zinc treatments prescribed; 5) ORS treatments prescribed and zinc treatments prescribed. For each VHW, these combinations should equal each other, in each month. If the two data points in each combination do not equal each other, this suggests an error in management for a patient in that category. We assessed concordance using month-by-month totals, and then summarized over the 2-year period. These calculations are

demonstrated in Figure 4, using the example of concordance between diarrhea patients seen and ORS treatments prescribed.

Concordance is an imperfect quality measure in that we cannot know, for instance, whether the diagnosed patients are the same individuals as the treated patients, but it provides a supplementary quality metric. Due to limitations in the aggregate data recorded, we are unable to assess concordance for pneumonia assessment and treatment (as there is no clear record in the aggregate data of the number of children who met respiratory rate criteria for presumed pneumonia).

## B. Sampling of individual patient visits

We use a stratified, unweighted sample to measure quality at the level of individual VHWs, and to provide optimal data for the primary analytic outcome (change over time in quality of care). To ensure a sufficient sample size for this approach, we used LQAS methods to establish the requisite stratum sample size (i.e., number of sampled records per VHW).

LQAS is a method originally used in industrial quality assurance, but which can also be applied to assessing data quality or quality of care. It was originally intended as a rapid and cost-effective quality assurance method for industrial production, in which items were often easily classified according to the "lot," or batch, in which they were produced (18). However, LQAS has more recently been applied as a monitoring and evaluation tool for a range of health programs (19), and specifically for data quality in VHW programs (20–22). An LQAS approach is useful in settings in which observations are naturally stratified. In this study, patient visits are stratified by VHW.

LQAS uses relatively small sample sizes, so it is not intended to produce precise quantitative estimates of individual performance. Rather, at the stratum (lot) level – in this case, at the level of the VHW – it allows for an approximate, binary determination of quality (high or low quality). However, the small samples (lots) can be combined into an overall dataset, allowing for more

precise, quantitative estimates of quality for the overall program (18). This resulting dataset is simply a stratified, unweighted sample.

Implementation of lot quality assurance sampling requires researchers or program managers to specify upper and lower thresholds for quality, as well as alpha and beta error bounds. Strata (or lots) with actual quality above the upper threshold should have a high probability of being classified as "high quality" while strata (or lots) with actual quality below the lower threshold should have a high probability of being classified as "low quality." We selected upper and lower thresholds of 0.9 and 0.7 (thus, 90% correct management is our target, and anything below 70% should definitely be regarded as poor quality), and alpha and beta error bounds of 0.1. Based on this information, the lot sample size and decision threshold can be calculated. Using the "LQAS Sampling Plan Calculator" (23), the lot size calculated is 25, with a decision rule of 20, meaning that VHWs with correct patient management of 21/25 (or better) are deemed as providing high-quality care, while those with 20/25 or fewer correct are deemed as not yet providing high-quality care.[3]

This sampling approach requires a full sampling frame, divided by the main variable of interest – in this case, by VHW (18). We created a paper-based sampling frame, in which copies of each VHW's 24 Sick Patient Registers (one from each month) were used to create a separate sampling frame for each VHW, by numbering all of the VHW's patient visits in temporal order. For each VHW, a random number generator was used to select 25 random numbers between 1 and X, with X being the total number of patient visits for a given VHW over the course of 2 years. Given the lack of a reliable unique identifier and the use of paper records from clinical care, we do not have a reliable way of tracking individual patients over time. Since a VHW may care for the same patient multiple times, it is possible that 2 different illness episodes for the same individual are included in the sample.

[3] Note that the lot quality assurance sampling methodology uses a decision rule lower than the upper threshold, so that lots with an actual quality of 90% have a high probability of being classified as "high quality;" thus, the decision rule is 21/25 = 84%, rather than a decision rule of 90%

After random selection of 25 patient visits per VHW, we then used a customized Research Electronic Data Capture (REDCap) database for data entry, hosted by Partners Healthcare (24). This database included multiple data validation steps in the user interface to maximize accurate data entry. After data entry, we undertook multiple data cleaning steps, including comparison of related variables (e.g., comparison of the "visit date" field with the separate "month" and "year" fields in patient records) as well as examination of outlier values, with comparison to the original paper records.

Using the iCCM care protocol (the "Job Aid"), we created a set of 9 decision rules for quality care that can be assessed from the Sick Patient Registers (Figure 3). Of note, the Sick Patient Registers do not contain any record of medication dosages (only the name of the medication provided), so provision of the correct age-based dosage could not be included as a quality measure. Logic statements in Stata were used to determine whether each patient received appropriate care according to these 9 decision rules (though not every rule applies to each patient, depending on the patient's presenting symptoms and clinical data). To verify the decision rules and logic statements used for automated determination of iCCM protocol compliance, 125 patient encounters were reviewed and hand-graded in comparison to the iCCM protocol, with 100% agreement with the automated determinations in Stata.

From the combined program dataset, we summarized disease-specific quality metrics for the overall program. Quality metrics included: 1) adherence to correct diagnostic protocol (performing an RDT for malaria for all patients presenting with fever, and measuring a respiratory rate for all patients presenting with cough/fast breathing); 2) appropriate prescribing practices (treating all patients diagnosed with malaria, pneumonia, or diarrhea; avoiding inappropriate prescriptions for patients not meeting diagnostic criteria); 3) appropriate referral practices in keeping with iCCM guidelines; 4) the proportion of VHWs currently providing high-quality care using the LQAS decision rule cutoff.

We next sought to assess whether the quality of iCCM care provided by VHWs changed over calendar time since initiation of iCCM services in this program, with a goal of understanding how VHWs' level of experience impacted quality of care. We hypothesized that two competing trends might affect this relationship: on the one hand, VHWs might gain confidence and competence over time in using the iCCM algorithm, but on the other hand, adherence to the algorithm might decline as VHWs become further removed from their initial iCCM training. To examine the trend in quality of care over time, we fit logistic regression models, with a generalized estimating equations (GEE) approach to account for correlation by VHW (25,26). Each randomly selected patient visit served as a unit of observation. Our primary outcome of interest was a dichotomous measure of correct management for each individual patient, as determined by the standards described above (see Figure 3 as well). Our exposure of interest was time since initiation of iCCM care in this program (defined as date of patient visit minus date of iCCM initiation, March 1, 2013). Initially, we graphically depicted the data to understand the relationship between VHW experience and quality of care. We identified an approximately linear relationship, with an inflection point (spline knot) at approximately 6 months after iCCM initiation.

To test this hypothesis and optimally explain the relationship of interest, we fit 3 models: 1) categorizing program duration into four, 6-month intervals; 2) modeling time as a continuous variable; and 3) modeling time as a continuous variable with a spline knot at 6 months. We then used quasi-likelihood under the independence model criterion (QIC) – a modification of the Akaike information criterion (AIC) so that it can be applied to GEE models – to assess goodness of fit of the two continuous models (27). We used post-estimation margins to estimate and compare the proportion of visits with correct management at different time points, as predicted by these models.

## C. Individual records of all patient visits with danger signs or rectal artesunate use recorded

We first identified all patients in the Sick Patient Registers who were recorded as presenting with danger signs or receiving rectal artesunate.[4] As with the LQAS database, we used a customized REDCap database for data entry, with built-in data validation steps to maximize accurate data entry. Likewise, after data entry, we undertook the same data cleaning steps, including comparison of related variables (e.g., comparison of the "visit date" field with the separate "month" and "year" fields in patient records) as well as examination of outlier values, with comparison to the original paper records. We used the same decision rules for quality care as above, and then summarized appropriateness of treatment and referral decisions.

### D. Informed consent and ethical approval

Ethical approval for this study was granted by the Partners Healthcare Institutional Review Board and Research Ethics Committee at the Mbarara University of Science and Technology. Since this study involves analysis of anonymized clinical records, specific informed consent was not obtained from patients or caregivers.

## Results

### A. Aggregate iCCM service delivery data

Patient population and summary of care provided

In the overall iCCM pilot program, 23 VHWs in 5 villages completed 5,462 patient visits over 2 years; 2,102 (38%) patients received evaluation/treatment within 24 hours (Table 1). There were 2,887 (53%) patients who presented with fever, 2,276 (42%) with cough/fast breathing, and 1,460 (27%) with diarrhea (percentages add to more than 100% since some patients presented with more than one complaint). There were 2,431 malaria diagnoses by RDT over the 2-year period (thus, 45% of all patients seen were diagnosed with malaria), with 1,023 negative

[4] All patients who received rectal artesunate should have danger signs recorded. We sampled all patients receiving rectal artesunate so that we could document the number of patients who received rectal artesunate inappropriately (i.e., without danger signs being recorded).

RDTs (thus, 70% of RDTs performed were positive). For malaria treatment, 2,380 (44%) patients were treated with oral ACT, and 36 (0.7%) treated with rectal artesunate. Due to limitations in the data, it is not possible to determine the number of patients diagnosed with pneumonia; however, 2,370 (43%) patients received amoxicillin. For diarrhea treatment, 1,555 (28%) patients were treated with ORS, and 1,554 (28%) treated with zinc. There were 560 (10%) patients referred to a health center, 0 medication reactions reported, and 2 (0.04%) deaths reported.[5] We also graphically examined total patients seen by month, as well as total diarrhea patients by month and total malaria patients by month, to assess for seasonal variation (Figures 8-10), but did not observe any reproducible trend by season.

On average, each VHW saw 237 patients (range 105-441) – an average of 126 presenting with fever (range 43-316), 99 with cough/fast breathing (range 40-221), and 63 with diarrhea (range 18-139); see Table 2. Each VHW performed an average of 106 positive RDTs (range 19-265) and 44 negative RDTs (range 5-102). On average, each VHW prescribed ACT 103 times (range 17-255), amoxicillin 103 times (range 41-244), ORS 68 times (range 23-138), and zinc 68 times (range 22-140).

Quality of care as measured by monthly concordance

Given the relatively small number of patients with each condition per VHW per month, we have used perfect monthly concordance as the standard measurement (since percentages may be misleading). Since there are 23 VHWs and 24 months of data, there are a total of 552 VHW-month combinations; however, due to missing data and some months in which some VHWs saw 0 patients in certain categories, all of the metrics described here have fewer than 552 data points.

For concordance between patients presenting with fever and patients receiving an RDT, there were 238 out of 500 (48%) VHW-month combinations with perfect concordance (Table 3). As

[5] Given that 1 case was found in the LQAS sample in which a medication reaction occurred, the reporting of 0 medication reactions in all patient visits must be incorrect.

with the results for overall concordance, this stems largely from extra RDTs being performed – there were only 45 (9%) VHW-month combinations with more fever patients than RDTs performed, compared to 217 (43%) with more RDTs performed than fever patients. Concordance between malaria diagnoses (i.e., positive RDT results) and malaria treatments prescribed was substantially higher – there were 420 out of 521 (81%) VHW-month combinations with perfect concordance. Concordance between patients presenting with diarrhea and patients treated with ORS and zinc was likewise high, with 368 out of 449 (82%) VHW-month combinations having perfect concordance for ORS, and 378 out of 449 (84%) for zinc.[6] Concordance between ORS prescriptions and zinc prescriptions was very high, with 441 out of 466 (95%) of VHW-month combinations having perfect concordance.[7]

When we combined the monthly concordance values and converted them to proportions (see Figure 4 for this formula), concordance between patients presenting with fever and patients receiving an RDT remained low, with only 2 out of 23 VHWs achieving >90% concordance (Table 4). However, as noted above, this stems largely from extra RDTs being performed. Concordance between malaria diagnoses (i.e., positive RDT results) and malaria treatments prescribed was much higher, with 18 of 23 VHWs achieving >90% concordance, while 9 out of 23 achieved >95% concordance.

Combined monthly concordance between patients presenting with diarrhea and patients treated with ORS was also high, with 15 out of 23 VHWs achieving >90% concordance; for concordance between patients presenting with diarrhea and patients treated with zinc, 16 out of 23 VHWs achieving >90% concordance (Table 4). Concordance between ORS treatments

[6] In fact, we do not expect perfect concordance between ORS usage and zinc usage, since patients with diarrhea and a danger sign are supposed to receive ORS and accompaniment/referral, but not zinc. However, of the 1460 patients presenting with diarrhea, only 13 were recorded as having a danger sign, so the impact of this discrepancy on concordance is limited.

[7] As above, we do not expect perfect concordance between ORS and zinc usage, since diarrhea patients with danger signs will receive ORS only, but the impact of this discrepancy on concordance is limited since there are very few patients with diarrhea and danger signs.

prescribed and zinc treatments prescribed was high, with 22 out of 23 VHWs achieving >90% concordance, and 19 out of 23 achieving > 95% concordance.

## B. Sampling of individual patient visits

Patient population and summary of care provided

Of the 575 patient visits sampled, 52% (286) were female patients while 48% (265) were male patients, with a mean age of 31 months (range 2 months – 5 years);[8] see Table 5. Of note, there were 66 (11%) patients in this sample who were 5 years old at the time of the visit, whereas the iCCM algorithm is intended only for children under 5 years of age. Patient visits were spread relatively evenly among the 5 villages in the iCCM pilot program, with 125 from Bugoye, 112 from Ihani, 125 from Kanyaminigo, 88 from Kikokera, and 125 from Muramba I (these numbers are not all multiples of 25, as one VHW switched villages partway through the 2-year period examined here).

In regard to presenting complaints, 293 (51%) patients presented with fever, 237 (41%) with cough/fast breathing, and 155 (27%) with diarrhea (percentages add to more than 100% as some patients presented with multiple complaints; see Table 5). Only 11 (2%) patients were recorded as presenting with "danger signs."

Younger children were less likely to present with fever – fever was recorded for 34% of children 2-11 months, compared with 49% of children 1-2 years old and 57% of children 3-5 years old (chi-squared = 14.83, p = 0.001; see Table 6). The age criteria described here are based on those used in the VHW "Job Aid." Children 2-11 months were more likely to present with cough/fast breathing, with 53% having that as a recorded complaint, compared with 45% in children 1-2 years old and 37% in children 3-5 years old (chi-squared = 7.56, p = 0.023). Children 2-11 months were also more likely to present with diarrhea, with 42% having diarrhea, compared to

[8] Due to a lack of standardization in reporting, VHWs recorded ages using inconsistent units (weeks, months, or years). For the purposes of analysis, all reported ages were converted to months; however, this will tend to underestimate actual ages – e.g., a patient who was reported as "3 years old" was assumed to be 36 months old, whereas the patient may have been anywhere between 36 and 47 months old.

25% among children 1-2 years old and 24% among children 3-5 years old (chi-squared = 11.72, p = 0.003).

In regard to clinical data, 356 (62%) patients received an RDT for malaria, with 255 positive tests and 101 negative tests; thus, 72% of RDTs performed were positive for malaria (Table 7). Of the 55 children ages 2-11 months for whom a respiratory rate was recorded, 47 (85%) had an elevated respiratory rate (50 breaths/minute or higher). Among children 1-5 years old, 215 had a respiratory rate recorded, and of those 181 (84%) had an elevated respiratory rate (40 breaths/minute or higher).

In regard to treatment provided and outcomes of care, 250 (43%) of patients received oral artemisin combination therapy (ACT) for malaria, 3 (0.5%) received rectal artesunate for suspected severe malaria, 239 (42%) received oral amoxicillin for pneumonia, 168 (29%) received ORS and 165 (29%) received zinc for diarrhea (Table 7). Of the 575 patient visits, 229 (40%) were recorded as having received evaluation/treatment within 24 hours of the onset of illness, and 66 (11%) were referred to a health facility. Only 1 (0.2%) medication reaction was recorded. There were no recorded deaths among the 575 sampled patient visits.

Quality of care – descriptive results

Of the 575 patient visits, 529 (92%) had a complete initial assessment recorded (defined as visit date, sex, and age recorded; if fever was a presenting complaint, then an RDT result was recorded; and if cough/fast breathing was a presenting complaint, then a respiratory rate was recorded; see Table 8). There were 14 (2%) patient visits for cough/fast breathing in which a respiratory rate was not recorded, and 10 (2%) patient visits for fever in which an RDT was not performed. Additionally, there were 73 patients who did not have fever recorded as a presenting complaint, but who nonetheless received an RDT.[9] Of 293 patients who presented with fever, 283 (97%) correctly received an RDT for malaria. Of 237 patients who presented with cough/fast breathing, 223 (94%) correctly had their respiratory rate recorded.

[9] This was not classified as an incomplete initial assessment in this study.

Of 255 patients with a positive RDT for malaria, 240 (94%) received correct management (Table 8).[10] There were 101 patients with a negative RDT, of whom only 44 (44%) received correct management; 56 patients with a negative RDT were not referred to a health center (of whom 3 also incorrectly received oral ACT), and 1 patient with a negative RDT and danger signs did not receive appropriate pre-referral treatment. Overall, 11 patients who did not have a positive RDT received ACT, out of 250 ACT prescriptions; thus, only 4% of ACT prescriptions were not indicated.

Of the 228 patient visits in which an elevated respiratory rate was documented, 216 (95%) were treated appropriately with amoxicillin. Additionally, 23 patients for whom a respiratory rate was not recorded, or who did not meet criteria for elevated respiratory rate, were treated with amoxicillin (out of 239 amoxicillin prescriptions); thus, 10% of amoxicillin prescriptions were not indicated.

Of 155 patient visits with diarrhea as a recorded complaint, 150 (97%) were managed appropriately with ORS and zinc. Additionally, 18 patients for whom diarrhea was not recorded as a presenting complaint were nonetheless treated with ORS or zinc. Given the retrospective analysis of VHW records, we are unable to determine whether the "overtreatment" observed here resulted from record-keeping errors (i.e., the VHW inadvertently omitted the treated condition as a presenting complaint) or a clinical error in treatment.

Of 11 patient visits with "danger signs" recorded, all 11 were documented as having been appropriately referred to a health center,[11] but only 4 had appropriate pre-referral treatment documented. However, the limited clinical documentation available prevents a conclusive analysis of the patients with danger signs (Table 8).

[10] This includes patients for whom fever was not recorded as a presenting complaint, but who nonetheless received an RDT and were found to have malaria.

[11] Note that this does not imply that the patient completed the referral; based on the available data, we cannot verify referral completion.

After combining all of the decision rules for correct management, over the 2-year period studied 75% (434) of patient visits had correct management. The proportion of patient visits with correct management was lowest in months 1-6 of the iCCM pilot, with 63% (96) of patients managed correctly, compared with 79% (116) in months 7-12, 76% (117) in months 13-18, and 85% (105) in months 19-24. This trend was driven substantially by improved performance in the treatment of malaria and pneumonia. In months 1-6, VHWs followed appropriate malaria treatment protocols in 77% (51) of relevant visits, compared with 93% (74) in months 7-12, 97% (66) in months 13-18, and 94% (50) in months 19-24. Similarly, in months 1-6 VHWs followed appropriate pneumonia treatment protocols in 73% (52) of visits, compared with 91% (48) in months 7-12, 91% (62) in months 13-18, and 92% (54) in months 19-24.

At the individual VHW level, according to the LQAS decision rule cutoff of 20 patients (out of 25), 9 VHWs are classified as providing high-quality care over the 2-year period, while 14 are classified as not yet providing high-quality care. The median proportion of patient visits managed correctly was 80%, with a range of 32% to 92%.

Quality of care and VHW experience – logistic regression models

We began by graphically depicting the data to examine the relationship between time since initiation of iCCM services and correct management of patients (Figures 5 and 6). As described above, initial graphs suggested a trend toward improved quality of care during the first 6 months, and a leveling off of the relationship thereafter. In our first model, categorizing time into four 6-month periods, we found significantly higher odds of correct patient management in months 7-12, 13-18, and 19-24, compared with months 1-6 ($p = 0.003$, $p = 0.032$, and $p = 0,001$, respectively; see Table 9). When we modeled time as a continuous variable, we estimated a 6% increased odds of correct management for each additional month since iCCM initiation (OR = 1.06, 95% CI 1.02-1.09, $p < 0.001$). However, when we added a spline knot at 6 months, we found a significant increase in the proportion of appropriate management per month in the first 6 months (OR = 1.24, 95% CI 1.08-1.43, $p = 0.003$), but not for months 7-24 (OR = 1.01, 95% CI

0.98-1.04, p = 0.47; see Table 9 and Figure 7). The QIC estimate comparing the continuous and spline models demonstrated an improved model fit after the addition of the spline term (QIC decreased from 614.6 to 612.2). Using post-estimation margins, the model with a spline term predicts an initial proportion of patients managed correctly of 50% (95% CI 36-64%), increasing to 78% (95% CI 70-87%) at 6 months, 80% (95% CI 73-86%) at 12 months, 81% (95% CI 75-87%) at 18 months, and 82% (95% CI 75-89%) at 24 months (see Figure 7).

## C. Individual records of all patient visits with danger signs or rectal artesunate use recorded

There were a total of 95 patient visits over 2 years with "danger signs" recorded as present (Table 10). Additionally, in 10 patient visits, rectal artesunate was prescribed even though danger signs were not recorded, implying incorrect use of this medication (or incorrect record-keeping). Of the 95 patient visits with danger signs recorded, 49 (52%) were female patients; mean age was 26 months (range 2 weeks – 5 years).[12] There was substantial variation in reporting of danger signs among VHWs; 3 VHWs accounted for half (48, or 51%) of the danger signs patients recorded.

In regard to presenting complaints, 45 (47%) patients with recorded danger signs presented with fever, 19 (20%) with cough/fast breathing, and 13 (14%) with diarrhea; 40 (42%) did not have any of these complaints recorded (percentages add to >100, as some patients presented with multiple complaints; see Table 10). In regard to clinical data, of the 95 patient visits with danger signs recorded, 53 (56%) patients received an RDT, of which 23 (43%) were positive for malaria. Of 3 patients 2-11 months with a recorded respiratory rate, 1 had an elevated respiratory rate (50 breaths/minute or higher); of 20 patients 1-5 years with a recorded respiratory rate, 16 had an elevated respiratory rate (40 breaths/minute or higher).

[12] As noted in the previous section, VHWs recorded ages using inconsistent units, so the conversion to months will tend to underestimate actual ages in the patient population.

Of the 95 patient visits with danger signs recorded, 22 (23%) received rectal artesunate, 7 (7%) received oral ACT, 6 (6%) received oral amoxicillin, 7 (7%) received ORS, and 5 (5%) received zinc (Table 10). Only 8 (8%) patients with danger signs were recorded as receiving evaluation/treatment within 24 hours of illness onset. Out of the 95 patients with danger signs, 90 (95%) were referred to a health center. There was 1 death recorded in patients with danger signs, and no adverse medication reactions. Of note, there were 33 (35%) patients for whom no clinical data or treatment was recorded – the patients were merely recorded as having danger signs and having been referred to the health center.

Of the 95 patient visits with danger signs recorded, 90 (95%) patients were appropriately referred to a health center, while 63 (66%) received appropriate pre-referral treatment based on the clinical information recorded (Table 11).[13] Of 45 patients presenting with fever and danger signs, 42 (94%) were referred appropriately, but only 22 (49%) received pre-referral treatment.[14] Of the 17 patients with elevated respiratory rate and danger signs, 16 (94%) were appropriately referred, but only 4 (24%) received pre-referral amoxicillin. Of 13 patients presenting with diarrhea and danger signs, 12 (92%) were appropriately referred, but only 5 (38%) received pre-referral ORS.

# Discussion

## A. Summary of key findings

Quality of care was high for the core steps involved in managing uncomplicated malaria, pneumonia, and diarrhea. Quality of care was substantially lower for referral of patients with fever who had negative RDTs, and for pre-referral treatment of patients with danger signs. In

[13] This may be an overestimate of actual quality, as 33 patients were recorded only as having danger signs and being referred; while there are some scenarios in which this combination is correct (and thus it is considered correct management according to our decision rules), it may also represent incomplete clinical evaluation or incomplete documentation by VHWs.

[14] This may be an overestimate of actual quality, as the iCCM protocols specify treatment with rectal artesunate or ACT based on the specific danger sign recorded; however, using retrospective record review, we cannot identify which danger sign was recorded, so we cannot measure whether these patients received the correct medication.

regard to the analytic results of this study, we demonstrated an encouraging improvement over time in VHWs' competence, at least over the initial 6-month period after iCCM implementation, after which point the proportion of patients managed appropriately seemed to plateau (though there was no indication of deterioration in quality later in the 2-year period).

The level of quality documented here is generally similar to prior studies that used record review to measure quality of care. For instance, in a recent multi-site study in Ghana, Burkina Faso, and Uganda, overall quality was lower, but quality at the Uganda site was very high (8). Likewise, quality of care for uncomplicated malaria and pneumonia documented here was similar to those documented in a recent study in Zambia (7). We documented higher quality of care for pneumonia than in the record review portion of another recent study in Uganda (10).

However, the high rates of quality for pneumonia care based on record review should be interpreted with caution, as we cannot account for VHWs' ability to measure respiratory rate appropriately, which is a significant reason for skepticism about the use of iCCM for pneumonia treatment (6). Additionally, in this study, over 80% of patients for whom a respiratory rate was recorded were found to have an elevated respiratory rate; this may indicate that some VHWs were overestimating respiratory rate, or were only recording elevated respiratory rates, though it is also possible that patients with more minor ailments are less likely to present to VHWs.

Patients with "danger signs" (signs of severe illness) almost always received appropriate referral to a health center. In contrast, in recent studies in Ethiopia and Malawi, roughly half of patients with signs of severe illness were referred (13,14). However, in our study, quality for pre-referral treatment of danger signs patients was low; as a result, overall correct management of danger signs patients was relatively low as well. Given the limited clinical information available, our results should be interpreted with caution, as they may overestimate quality of pre-referral treatment since we could not assess all aspects of correct pre-referral treatment.

The single most common error made by VHWs, comprising nearly 40% of the patient visits with incorrect management, was failure to refer patients with a fever for whom the malaria RDT was negative (and who did not have danger signs). This may result from a misunderstanding of the iCCM protocol, a belief that these families are unlikely to visit a health center if referred, a reluctance to refer patients who are relatively likely to have a self-limiting viral infection, or some other reason. Further elucidation of VHW perspectives is needed to understand the reasons for this error. Of note, in some versions of the iCCM algorithm, patients presenting with fever who have a negative RDT (and no danger signs or fast breathing) receive symptomatic management and follow-up in the community, rather than referral to a health center, with high rates of spontaneous improvement (7).

Overuse of antimalarials and antibiotics was relatively low in this study, with 4% inappropriate use of ACT and 10% overuse of amoxicillin. These rates are slightly higher than in the trial in Ethiopia discussed above (14), and broadly comparable to the multi-site trial in Ghana, Burkina Faso, and Uganda, which found higher levels of overuse in Ghana and Burkina Faso, but very low levels of overuse in Uganda (8).

The LQAS results demonstrate substantial variation in quality among VHWs. As a monitoring tool, this may offer a useful means of identifying VHWs who would benefit from additional training and mentorship. While the final LQAS result, in which only 9 of 23 VHWs are classified as providing high-quality care, may seem disconcerting, the analytic results of this study document an encouraging trend toward improvement in quality in the initial months of iCCM implementation. Due to our sample size, we could not repeat the LQAS assessment in a rigorous way using only months 7-24. Additionally, some of the errors documented here have very limited risk of harm, such as extra prescription of ORS or zinc. LQAS becomes more useful when it is used as a repeated measure after quality improvement efforts, a step we plan to take in coming years in this program.

To our knowledge, there are no prior studies that have used the approach of measuring VHW-level concordance to assess quality of care. While this approach is somewhat imprecise, we feel it has value nonetheless as a scalable solution, given the ease of measurement in settings with existing aggregate data. Overall, quality as measured by concordance was high. In addition, 2 of the errors that decreased concordance are likely of low clinical consequence – overuse of RDTs for malaria and overuse of ORS. While we used statistical software, this approach could be easily implemented using Microsoft Excel or a similar program.

While it was not a pre-defined quality metric in this study, it is worth noting that over 10% of patients sampled were 5 years old, whereas the iCCM protocol is intended only for children under 5 years old. This may result from ambiguity in the "Sick Child Job Aid" used by VHWs in Bugoye, which often lists age ranges that appear inclusive of 5 year olds (i.e., "children 1-5 years" or "children 4-5 years"). Given this ambiguity, we did not treat this as an error by VHWs (i.e., cases in which VHWs cared for 5-year old patients were evaluated in the same way as any other patient, rather than being automatically classified as incorrect based on the child's age). However, since the dosing algorithms are intended for younger children, this practice may put patients at risk of sub-therapeutic drug levels.

## B. Limitations

This study has a number of significant limitations, in part resulting from our use of routine clinical records as the data source. First, and perhaps most importantly, in this study we are assessing quality of documented care, which may differ from the quality of actual care provided. It is unclear whether this will tend to underestimate or overestimate quality. We are unable to assess whether VHWs performed RDTs correctly or measured respiratory rate accurately, so in that respect these results may overestimate quality of care. Conversely, in a program in which some VHWs have limited literacy skills, some patients may have received correct care but incorrect documentation – for instance, patients who received ORS or zinc, but did not have diarrhea listed as a presenting complaint, are considered to have received incorrect management according to the decision rules used here, but it is quite possible that

this was simply a record-keeping error. Second, based on the limited clinical data recorded by VHWs, we cannot assess all relevant dimensions of quality. For instance, we cannot assess whether the correct medication dosage was administered or whether the caregiver received proper instructions. Likewise, since the specific "danger sign" is not recorded on the clinical form used, we are limited in our ability to characterize the management of this subset of patients, who likely face the highest risk of mortality. Third, data quality is a potential concern, especially for the aggregate data used to assess concordance, since we used existing data that had been entered previously, limiting our ability to undertake data validation steps.

In regard to the study design, the decision rules for quality care do not differentiate between errors with low potential for harm (e.g., prescribing ORS when it is not needed) and errors with high potential for harm (e.g., failure to treat a malaria patient). We considered a system with classification of "major errors" and "minor errors," but given our desire to create a simple and scalable system, we opted for a binary determination of correct or incorrect. Similarly, because ages were not recorded in a standardized way, we converted all ages to the unit of months; however, this will tend to underestimate actual age, since a 2-year-old child is assumed to be 24 months old, when in reality that child could be 24-35 months old. As a result, caution is advised in comparing the age distributions described here to other populations. Additionally, there is a certain subjectivity in deciding what errors count as incorrect management. For instance, there were 73 patients who did not have fever recorded as a presenting complaint, but who nonetheless received an RDT. We did not classify this as incorrect management, given the limited harm of an RDT, especially in a population with such high malaria incidence. If this had been considered an error, then the proportion of cases with correct management would have been somewhat lower. As noted above, we also did not consider treatment of a 5-year-old child to be incorrect management, given the ambiguity in the "Job Aid" used by VHWs.

For the analytic outcome of change in quality over time, the small number of VHWs in the iCCM pilot program prevents further analysis of other factors, such as education level of VHWs or patient volume. Additionally, there may be important trends in quality of care over time that

arise outside the 2-year period observed here. Finally, as noted previously, due to the lack of a reliable unique identifier, we cannot exclude the possibility that 2 different illness episodes for the same individual are included in the sample of patient visits. However, the impact of this issue is likely small, since the 2 visits for a given patient are not necessarily correlated with respect to quality of care.

## Conclusions

This study yields several significant practical results. First, it demonstrates the feasibility of measuring iCCM quality of care using routine data. LQAS requires additional data entry, but the relatively small sample sizes make it less costly than more exhaustive data entry. In settings such as this one where aggregate data are already recorded, the concordance approach requires no additional data entry. Second, it provides initial results on the trend in quality of iCCM care over time – a topic highly relevant to the training and supervision needs of VHWs as iCCM programs expand in Uganda and elsewhere. Further evaluation may clarify the impact of patient volume on this trend, with implications for the size of the catchment area assigned to each VHW. Third, it demonstrates opportunities for the Ugandan Ministry of Health to improve iCCM protocols – for instance, by clarifying the age cutoffs on the "Job Aid" and by improving the training and the "Job Aid" on areas that VHWs seem to find confusing, such as treatment of "danger signs" patients and referral of patients with negative RDTs. Additionally, it demonstrates areas in which more detailed data collection on iCCM patients could be useful, such as identification of specific danger signs or medication dosages. On a broader level, it bolsters the evidence for iCCM programs that address at least 3 diseases (as opposed to single disease programs), given the high quality of care for uncomplicated malaria, pneumonia, and diarrhea, and the trend toward initial improvement over time.

## Suggestions for future work

This study also raises a number of important research questions. First, it offers initial answers about the relationship between quality of care and time since initial training. A larger sample size with long-term follow-up would provide more conclusive information, and would allow for assessment of VHW-level factors such as level of education and patient volume. The iCCM program in Bugoye is now expanding to 8 villages, so we hope to use this opportunity to evaluate the larger program over time. With a larger dataset, it would also be possible to chart different components of quality over time (e.g., malaria care, pneumonia care, diarrhea care), to focus on areas that need review at refresher trainings. Within a larger program – likely one larger than the expanded program in Bugoye – one could also track the effect of different training and supervision systems on quality of care over time. The LQAS approach will also become more meaningful with repeated measurements, and will provide an important means of documenting the impact of quality improvement efforts.

Second, the question of the relationship between patient volume and quality of care requires a larger VHW program to evaluate more fully as well. Different VHW programs assign widely varying numbers of households to their VHWs; there is limited evidence on the optimal number of households for different program goals. Gaining a greater understanding of the optimal number of patient visits to achieve consistent competence would thus inform the design of iCCM programs more broadly.

Third, while there are significant advantages to measuring quality using routine data, some components of quality cannot be measured in this way, such as competence in performing at RDT or measuring respiratory rate accurately. While prior evaluations have employed direct observation of VHWs or re-examination of their patients by a physician or other healthcare worker, this approach is time-consuming, costly, and takes healthcare workers away from other duties. We suggest that video-based approaches for measurement of respiratory rate, as well as peer support using a checklist for RDT competence, may achieve similar outcomes. We hope to pilot these approaches in the expanded Bugoye iCCM program.

Finally, we suggest a role for qualitative research into VHW perspectives on their work. Qualitative interviews may elucidate the reasons behind errors identified here, such as low quality of pre-referral treatment for “danger signs” patients, the failure to refer febrile patients with negative RDTs, reasons for antimalarial or antibiotic overuse, or other issues. Qualitative interviews may also help to identify factors that affect the development of competence over time, such as informal peer networks among VHWs, as well as strategies to improve VHW training sessions. While high-quality qualitative research takes a substantial investment of time and resources, more informal interviews using a standardized discussion guide may provide iCCM program leadership with valuable feedback for quality improvement.

## Summary

Integrated Community Case Management (iCCM) is an approach to providing care for malaria, pneumonia, and diarrhea in children under 5 years of age. It is often focused on increasing access to care in rural areas of developing countries. In iCCM programs, village health workers, who are often community members who volunteer part-time to do this work, use written protocol to guide them through the evaluation and treatment of these illnesses. The ultimate goal of such programs is to make prompt care more accessible, thus decreasing the delays in care that might increase the risk of death for children with these illnesses. In this study, we examine quality of iCCM care in a small program in rural Uganda. There are several approaches to measuring quality of iCCM care. This research study proposes simple, low-cost ways of using clinical records and summary data to measure quality. As Uganda and other countries expand iCCM programs, these methods could be used to measure quality in a way that does not require dedicated research funding. In addition, we assess how VHWs' performance changes over time. Our findings suggest that quality of care increases during the first 6 months after iCCM implementation, but then becomes relatively constant after that. These results suggest that more intensive supervision and support may be necessary in the early months of iCCM implementation to ensure that patients receive high-quality care.

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## Tables and figures

Table 1: Summary of patient demographics and care provided for all iCCM patients

| Characteristic | N (%) |
|---|---|
| Total patient visits | 5462 (100%) |
| *Presenting complaints** | |
| Fever | 2887 (53%) |
| Cough/fast breathing | 2276 (42%) |
| Diarrhea | 1460 (27%) |
| Patients with danger signs** | 90 (2%) |
| Patients receiving RDT for malaria | 3454 (63%) |
| Positive RDTs | 2431 (70%) |
| Negative RDTs | 1023 (30%) |
| Patients receiving oral ACT | 2380 (44%) |
| Patients receiving rectal artesunate | 36 (0.7%) |
| Patients receiving oral amoxicillin | 2370 (43%) |
| Patients receiving ORS | 1555 (28%) |
| Patients receiving zinc | 1554 (28%) |
| Patients treated with 24 hours of illness onset | 2102 (38%) |
| Patients referred to health center | 560 (10%) |
| Medication reactions*** | 0 (0%) |
| Deaths | 2 (0.04%) |

* Percentages add to >100%, as some patients presented with multiple complaints

** 95 danger signs patients were identified in the Sick Patient Registers, indicating that 5 patients were missed in the aggregate data

*** Given that 1 case was found in the LQAS sample in which a medication reaction occurred, the reporting of 0 medication reactions in all patient visits must be incorrect

Table 2: Summary of aggregate data by VHW

| Measure | Mean (range) |
|---|---|
| Total patients per VHW | 237 (105-441) |
| Fever patients per VHW | 126 (43-316) |
| Cough/fast breathing patients per VHW | 99 (40-221) |
| Diarrhea patients per VHW | 63 (18-139) |
| Total RDTs per VHW | 150 (56-343) |
| Positive RDTs per VHW | 106 (19-265) |
| Negative RDTs per VHW | 44 (5-102) |
| ACT prescriptions per VHW | 103 (17-255) |
| Amoxicillin prescriptions per VHW | 103 (41-244) |
| ORS prescriptions per VHW | 68 (23-138) |
| Zinc prescriptions per VHW | 68 (22-140) |

Table 3: Quality of care as measured by monthly concordance

| Measure | VHW-month combinations | | |
|---|---|---|---|
| | Perfect concordance | Relevant combinations | % perfect concordance |
| Patients presenting with fever and patients receiving RDT for malaria | 238 | 500 | 48% |
| Positive RDTs (i.e., malaria diagnoses) and malaria treatments prescribed | 420 | 521 | 81% |
| Patients presenting with diarrhea and ORS treatments prescribed | 368 | 449 | 82% |
| Patients presenting with diarrhea and zinc treatments prescribed | 378 | 449 | 84% |
| ORS treatments prescribed and zinc treatments prescribed | 441 | 466 | 95% |

Table 4: Quality of care as measured by aggregate concordance for each VHW over 2 years

| Measure | VHWs achieving >90% concordance | VHWs achieving >95% concordance |
|---|---|---|
| Patients presenting with fever and patients receiving RDT for malaria | 2 (9%) | 1 (4%) |
| Positive RDTs (i.e., malaria diagnoses) and malaria treatments prescribed | 18 (78%) | 9 (39%) |
| Patients presenting with diarrhea and ORS treatments prescribed | 15 (65%) | 8 (35%) |
| Patients presenting with diarrhea and zinc treatments prescribed | 16 (70%) | 9 (39%) |
| ORS treatments prescribed and zinc treatments prescribed | 22 (96%) | 19 (83%) |

Table 5: Patient demographics and presenting conditions for LQAS sample (overall n = 575)

| Characteristic | N (%) or Mean (Range) |
|---|---|
| Female | 286 (52%) |
| Age | 31 months (2 months - 5 years) |
| *Village* | |
| Bugoye | 125 (22%) |
| Ihani | 112 (19%) |
| Kanyaminigo | 125 (22%) |
| Kikokera | 88 (15%) |
| Muramba I | 125 (22%) |
| *Presenting complaints** | |
| Fever | 293 (51%) |
| Cough/fast breathing | 237 (41%) |
| Diarrhea | 155 (27%) |
| Other | 66 (11%) |
| Patients with danger signs | 11 (2%) |

* Percentages add to >100%, as some patients presented with multiple complaints

Table 6: Presenting conditions by age group in LQAS sample (overall n = 575)

| Condition | % (n) | | | chi-squared | p-value |
|---|---|---|---|---|---|
| | 2-11 months | 1-2 years | 3-5 years | | |
| Fever | 34% (31) | 49% (88) | 57% (165) | 14.83 | p = 0.001 |
| Cough/fast breathing | 53% (48) | 45% (81) | 37% (108) | 7.56 | p = 0.023 |
| Diarrhea | 42% (38) | 25% (46) | 24% (69) | 11.72 | p = 0.003 |

Table 7: Clinical data, care, and outcomes for LQAS sample (overall n = 575)

| Measure | N (%) |
|---|---|
| Patients receiving RDT for malaria | 356 (62%) |
| Positive RDTs | 255 (72%) |
| Negative RDTs | 101 (28%) |
| *Respiratory rate - patients 2-11 months (n = 91)* | |
| Respiratory rate measured | 55 (60%) |
| Respiratory rate elevated | 47 (52%) |
| *Respiratory rate - patients 1-5 years (n = 471)* | |
| Respiratory rate measured | 215 (46%) |
| Respiratory rate elevated | 181 (38%) |
| Patients receiving oral ACT | 250 (43%) |
| Patients receiving rectal artesunate | 3 (0.5%) |
| Patients receiving oral amoxicillin | 239 (42%) |
| Patients receiving ORS | 168 (29%) |
| Patients receiving zinc | 165 (29%) |
| Patients treated with 24 hours of illness onset | 229 (40%) |
| Patients referred to health center | 66 (11%) |
| Medication reactions | 1 (0.2%) |
| Deaths | 0 (0%) |

Table 8: Quality of care in LQAS sample

| Measure | N (%) |
|---|---|
| Complete initial assessment (n = 575) | 529 (92%) |
| RDT performed for patient presenting with fever (n = 293) | 283 (97%) |
| Respiratory rate recorded for patient presenting with cough/fast breathing (n = 237) | 223 (94%) |
| Malaria patients receiving correct management (n = 255) | 240 (94%) |
| Patients with negative RDT receiving correct management (n = 101) | 44 (44%) |
| Patients with elevated respiratory rate receiving correct treatment (n = 228) | 216 (95%) |
| Patients with diarrhea receiving ORS and zinc (n = 155) | 150 (97%) |
| | |
| Patients inappropriately treated with ACT (n = 575) | 11 (2%) |
| Patients inappropriately treated with amoxicillin (n = 575) | 23 (4%) |
| Patients inappropriately treated with ORS, zinc, or both (n = 575) | 18 (3%) |
| | |
| Patients with danger signs appropriately referred to health center (n = 11) | 11 (100%) |
| Patients with danger signs receiving appropriate pre-referral treatment (n = 11) | 4 (36%) |
| | |
| Patients receiving overall correct management (n = 575) | 434 (75%) |
| Patients receiving overall correct management in months 1-6 of iCCM implementation (n = 152) | 96 (63%) |
| Patients receiving overall correct management in months 7-12 of iCCM implementation (n = 146) | 116 (79%) |
| Patients receiving overall correct management in months 13-18 of iCCM implementation (n = 154) | 117 (76%) |
| Patients receiving overall correct management in months 19-24 of iCCM implementation (n = 123) | 105 (85%) |
| | |
| VHWs providing high-quality care over 2 years, according to LQAS decision rules (n = 23) | 9 (39%) |

Table 9: GEE logistic regression models for overall quality of care over time

| Variable | OR | 95% CI | p-value | Model QIC* |
|---|---|---|---|---|
| *Model 1: Biannual groupings, with Months 1-6 as reference group* | | | | n/a |
| Months 7-12 | 2.33 | (1.33, 4.11) | p = 0.003 | |
| Months 13-18 | 1.84 | (1.05, 3.20) | p = 0.032 | |
| Months 19-24 | 3.05 | (1.76, 5.29) | p < 0.001 | |
| *Model 2: Time as a continuous variable* | | | | 614.62 |
| Months since iCCM services initiation | 1.06 | (1.02, 1.09) | p < 0.001 | |
| *Model 3: Time as a continuous variable, with a spline knot at month 6* | | | | 612.16 |
| Months since iCCM services initiation - Months 1-6 | 1.24 | (1.08, 1.43) | p = 0.003 | |
| Months since iCCM services initiation - Months 7-24 | 1.01 | (0.98, 1.04) | p = 0.47 | |

* Quasi-likelihood under the independence model criterion (QIC). This is a modification of the Akaike information criterion (AIC) so that it can be applied to GEE regression models to assess goodness of fit of different models. A lower QIC term reflects a better-fitting regression model. It is not applicable when using factor variables, so it is not calculated for Model 1, which uses a categorical time variable.

Table 10: Summary of all patients with "danger signs" recorded (overall n = 95)

| Characteristic | N (%) or Mean (range) |
|---|---|
| Female | 49 (52%) |
| Age | 26 months (2 weeks - 5 years) |
| *Presenting complaints** | |
| Fever | 45 (47%) |
| Cough/fast breathing | 19 (20%) |
| Diarrhea | 13 (14%) |
| Other | 40 (42%) |
| Patients receiving RDT for malaria | 53 (56%) |
| Positive RDTs | 23 (43%) |
| Negative RDTs | 30 (57%) |
| *Respiratory rate - patients 2-11 months (n = 14)* | |
| Respiratory rate measured | 3 (21%) |
| Respiratory rate elevated | 1 (7%) |
| *Respiratory rate - patients 1-5 years (n = 88)* | |
| Respiratory rate measured | 20 (23%) |
| Respiratory rate elevated | 16 (18%) |
| Patients receiving oral ACT (for malaria) | 7 (7%) |
| Patients receiving rectal artesunate | 22 (23%) |
| Patients receiving oral amoxicillin | 6 (6%) |
| Patients receiving ORS | 7 (7%) |
| Patients receiving zinc | 5 (5%) |
| Patients treated with 24 hours of illness onset | 8 (8%) |
| Patients referred to health center | 90 (95%) |
| Medication reactions | 0 (0%) |
| Deaths | 1 (1%) |

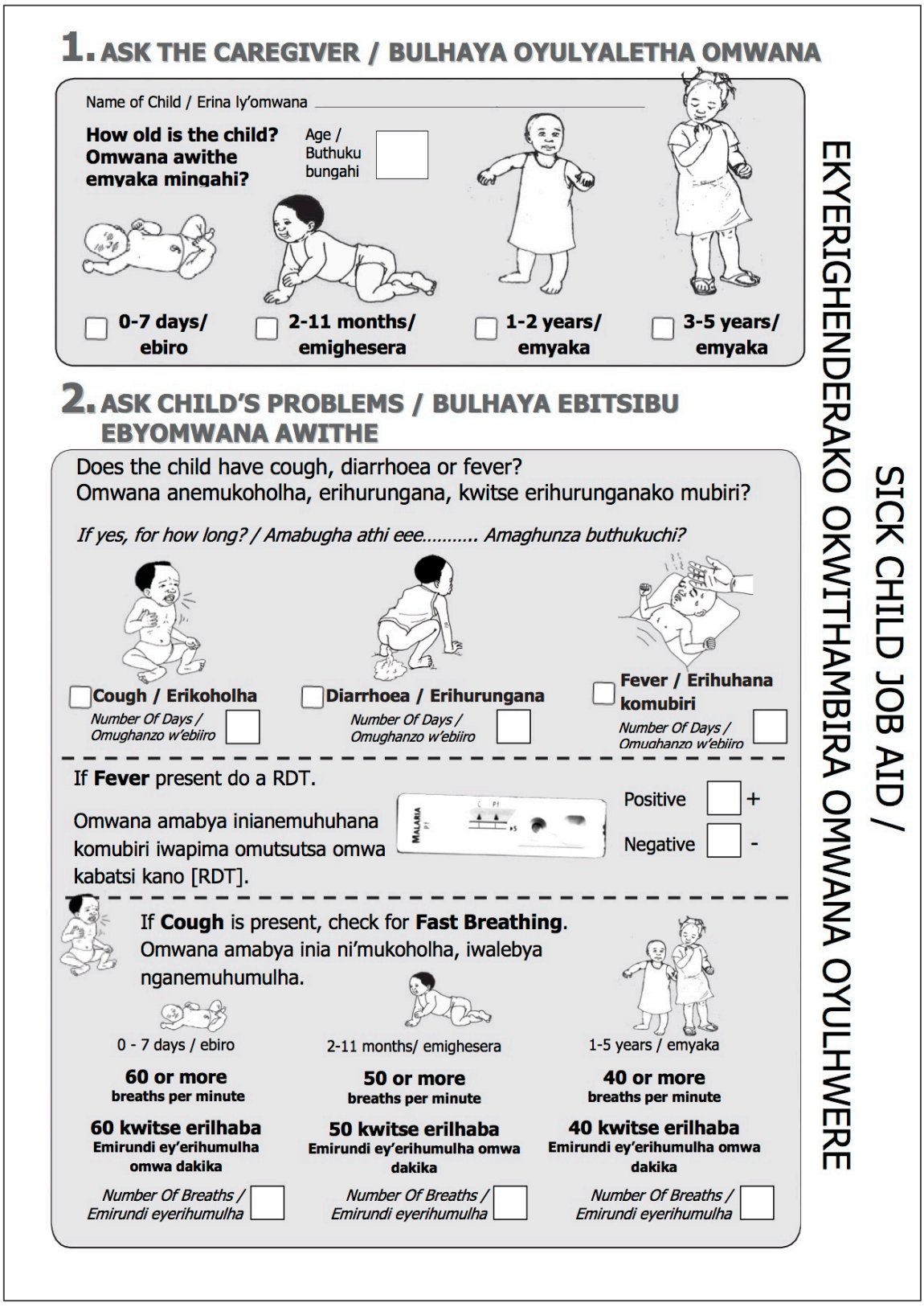
* Percentages add to >100%, as some patients presented with multiple complaints

** Given that 1 case was found in the LQAS sample in which a medication reaction occurred, the reporting of 0 medication reactions in all patient visits must be incorrect

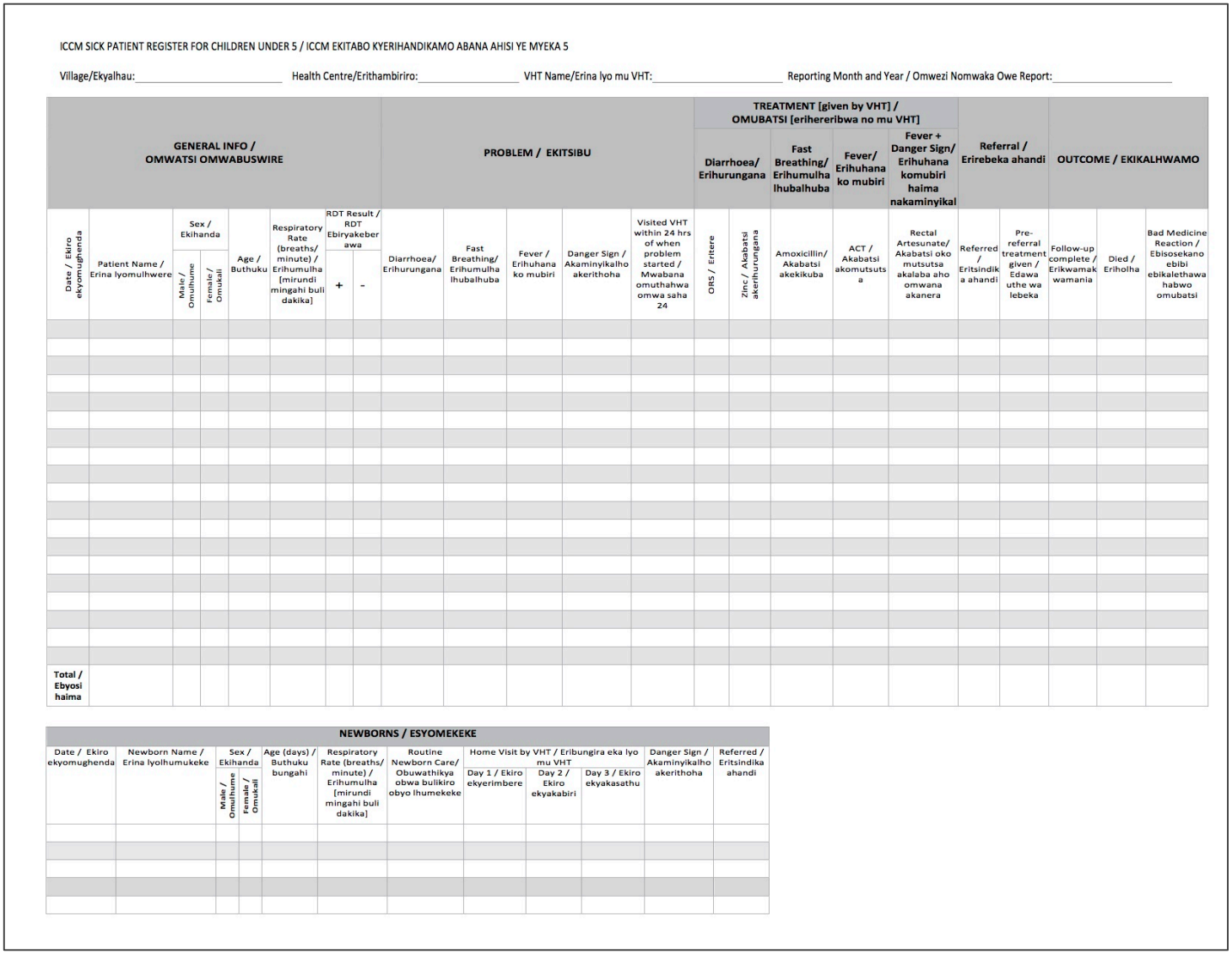
Table 11: Quality of care for all "danger signs" patients (overall n = 95)

| Measure | N(%) |
|---|---|
| Patients appropriately referred to health center | 90 (95%) |
| Patients receiving appropriate pre-referral treatment | 63 (66%) |
| *Fever patients with danger signs (n = 45)* | |
| Referred appropriately to health center | 42 (94%) |
| Received correct pre-referral treatment | 22 (49%) |
| *Patients with elevated respiratory rate and danger signs (n = 17)* | |
| Referred appropriately to health center | 16 (94%) |
| Received correct pre-referral treatment | 4 (24%) |
| *Patients with diarrhea and danger signs (n = 13)* | |
| Referred appropriately to health center | 12 (92%) |
| Received correct pre-referral treatment | 5 (38%) |

**Figure 1. Sample page from iCCM "Sick Child Job Aid"**



## Figure 2. Sample blank Sick Patient Register



ICCM SICK PATIENT REGISTER FOR CHILDREN UNDER 5 / ICCM EKITABO KYERIHANDIKAMO ABANA AHISI YE MYEKA 5

Village/Ekyalhau:_____ Health Centre/Erithambiriro:_____ VHT Name/Erina lyo mu VHT:_____ Reporting Month and Year / Omwezi Nomwaka Owe Report:_____

| GENERAL INFO / OMWATSI OMWABUSWIRE | | | | | | | | PROBLEM / EKITSIBU | | | | | TREATMENT [given by VHT] / OMUBATSI [erihereribwa no mu VHT] | | | | | Referral / Erirebeka ahandi | | OUTCOME / EKIKALHWAMO | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | | | | Diarrhoea/ Erihurungana | | Fast Breathing/ Erihumulha lhubalhuba | Fever/ Erihuhana ko mubiri | Fever + Danger Sign/ Erihuhana komubiri haima nakaminyikal | | | | |
| Date / Ekiro ekyomughenda | Patient Name / Erina lyomulhwere | Sex / Ekihanda | | Age / Buthuku | Respiratory Rate (breaths/ minute) / Erihumulha [mirundi mingahi buli dakika] | RDT Result / RDT Ebiryakeberawa | | Diarrhoea/ Erihurungana | Fast Breathing/ Erihumulha lhubalhuba | Fever / Erihuhana ko mubiri | Danger Sign / Akaminyikalho akerithoha | Visited VHT within 24 hrs of when problem started / Mwabana omuthahwa omwa saha 24 | ORS / Eritere | Zinc / Akabatsi akerihurungana | Amoxicillin/ Akabatsi akekikuba | ACT / Akabatsi akomutsutsa | Rectal Artesunate/ Akabatsi oko mutsutsa akalaba aho omwana akanera | Referred / Eritsindika ahandi | Pre-referral treatment given / Edawa uthe wa lebeka | Follow-up complete / Erikwamak wamania | Died / Eriholha | Bad Medicine Reaction / Ebisosekano ebibi ebikalethawa habwo omubatsi |
| | | Male / Omulhume | Female / Omukali | | | + | - | | | | | | | | | | | | | | | |
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| Total / Ebyosi haima | | | | | | | | | | | | | | | | | | | | | | |

| NEWBORNS / ESYOMEKEKE | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Date / Ekiro ekyomughenda | Newborn Name / Erina lyolhumukeke | Sex / Ekihanda | | Age (days) / Buthuku bungahi | Respiratory Rate (breaths/ minute) / Erihumulha [mirundi mingahi buli dakika] | Routine Newborn Care/ Obuwathikya obwa bulikiro obyo lhumekeke | Home Visit by VHT / Eribungira eka lyo mu VHT | | | Danger Sign / Akaminyikalho akerithoha | Referred / Eritsindika ahandi |
| | | Male / Omulhume | Female / Omukali | | | | Day 1 / Ekiro ekyerimbere | Day 2 / Ekiro ekyakabiri | Day 3 / Ekiro ekyakasathu | | |
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**Figure 3. Decision rules for quality care**

1. If fever is recorded: then RDT is performed*
2. If fast breathing is recorded: then respiratory rate is recorded
3. If danger signs are recorded: then patient is recorded as referred
4. If danger signs are recorded: then appropriate pre-referral treatment is given
    a. If fever and danger signs are recorded: then patient is treated with rectal artesunate or ACT**
    b. If fast breathing and danger signs are recorded: then patient is treated with amoxicillin
    c. If diarrhea and danger signs are recorded: then patient is treated with ORS
5. If RDT is positive, then patient is treated for malaria (with an oral ACT or rectal artesunate).
    a. If RDT is recorded as positive and no danger signs recorded: then patient is treated with an oral ACT
    b. If RDT is recorded as positive and danger signs are recorded: then patient is treated with rectal artesunate or oral ACT**
6. If fever is recorded, RDT is negative, and danger signs are not recorded: then patient is not treated for malaria and is recorded as referred.
7. If respiratory rate is above the age-based cutoff: then patient is treated with amoxicillin
8. If respiratory rate is below the age-based cutoff: then patient is not treated with amoxicillin.
9. If diarrhea is recorded: then patient receives appropriate treatment
    a. If diarrhea is recorded and danger signs are not recorded: then patient is treated with ORS and zinc.
    b. If diarrhea is recorded and danger signs are recorded, then patient is treated with ORS and referred.

*Performing an RDT without recording fever as present is not considered low-quality care in the above framework, given that the harm of an unneeded RDT is limited.

**From the Sick Patient Register, we are unable to determine whether recorded danger sign was “fever > 7 days, requiring ACT” or “seizure/altered level of consciousness/other danger sign requiring rectal artesunate,” so both rectal artesunate and oral ACT must be considered correct.

**Figure 4. Approach to calculating concordance**

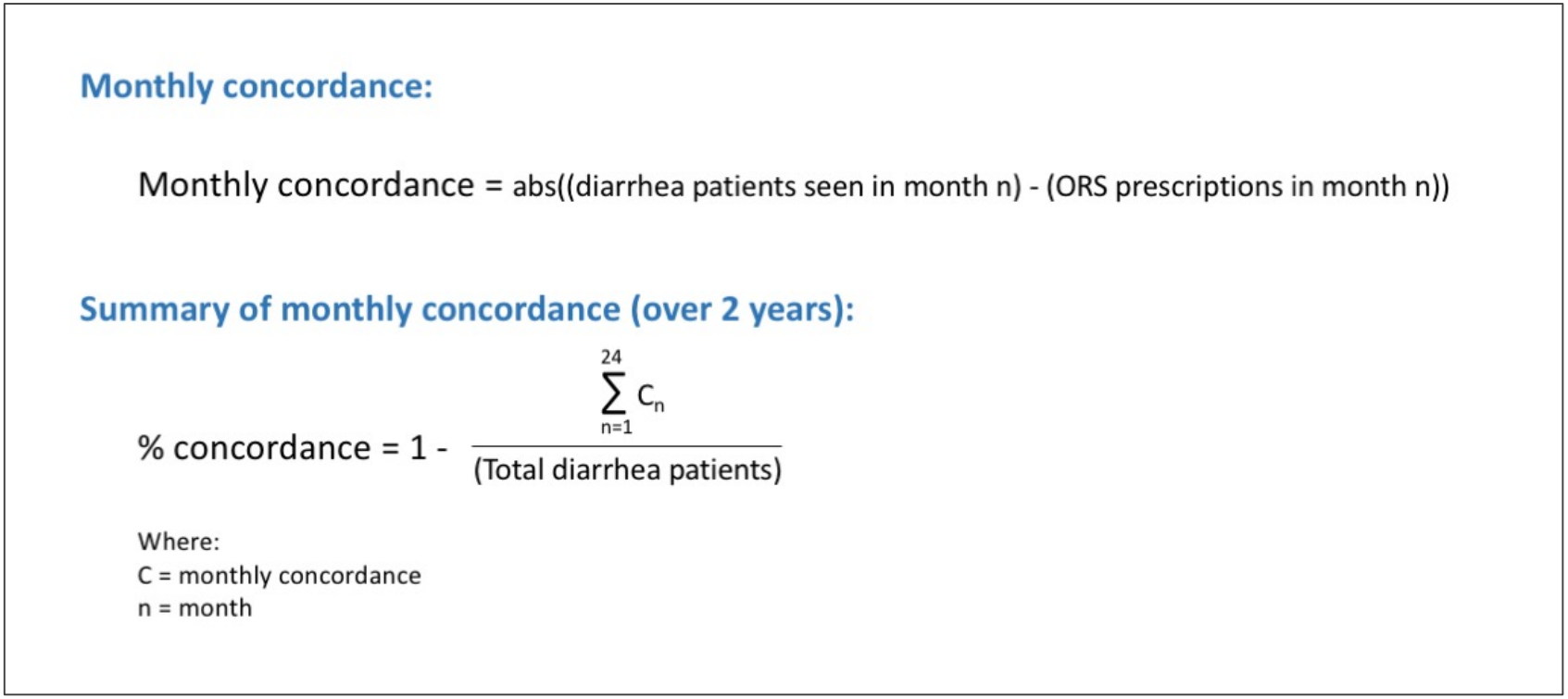


**Figure 5. Correct management over time – Lowess plot**

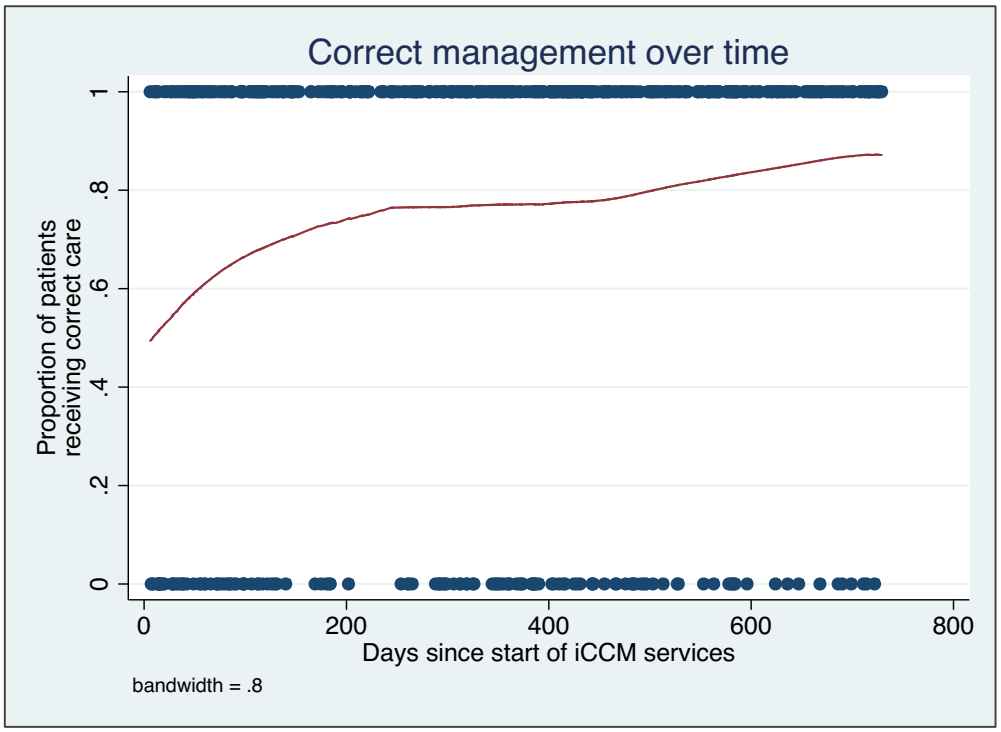



**Figure 6. Correct management over time – by biannual groupings**

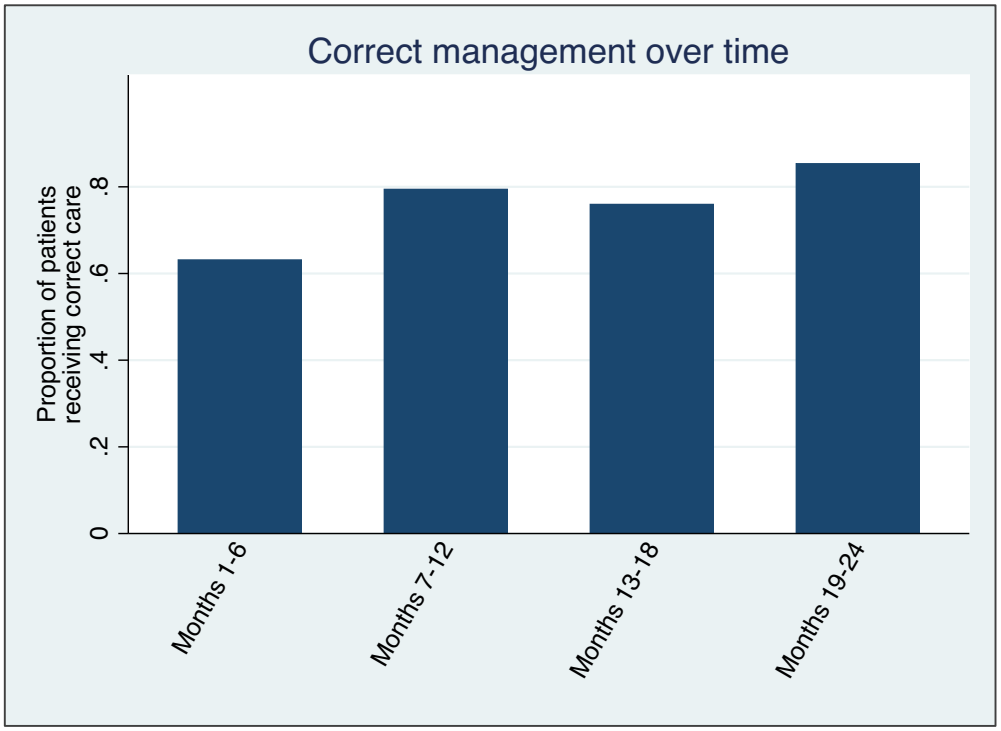


**Figure 7. Post-estimation margins plot of regression model with spline knot at 6 months**

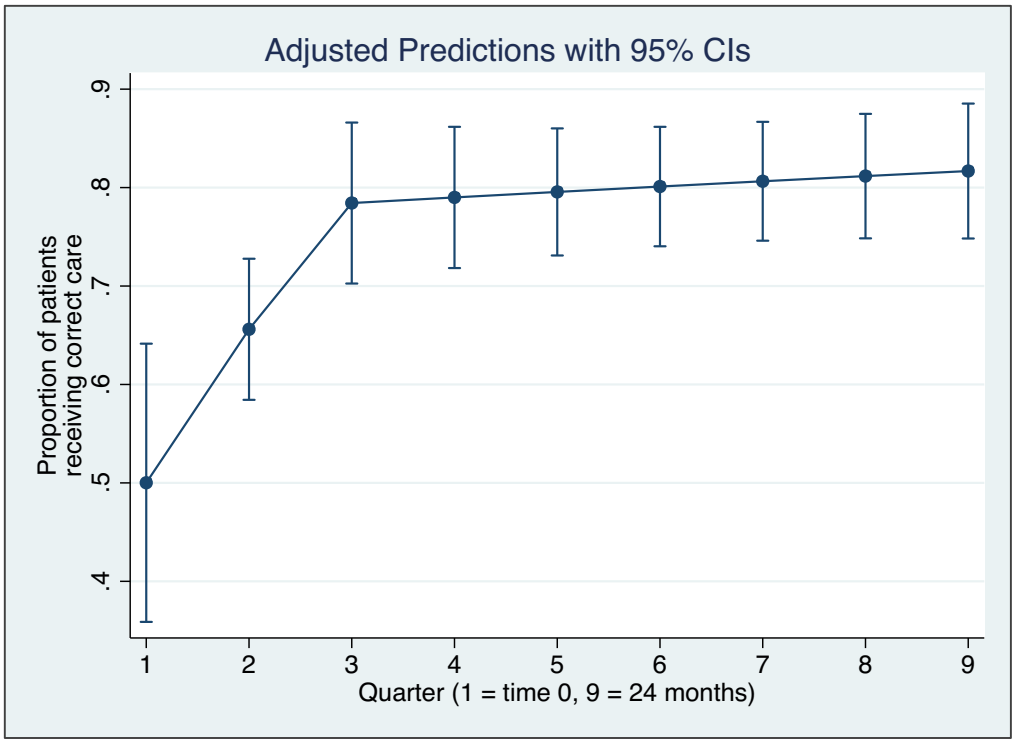



**Figure 8. Total patients seen by month**

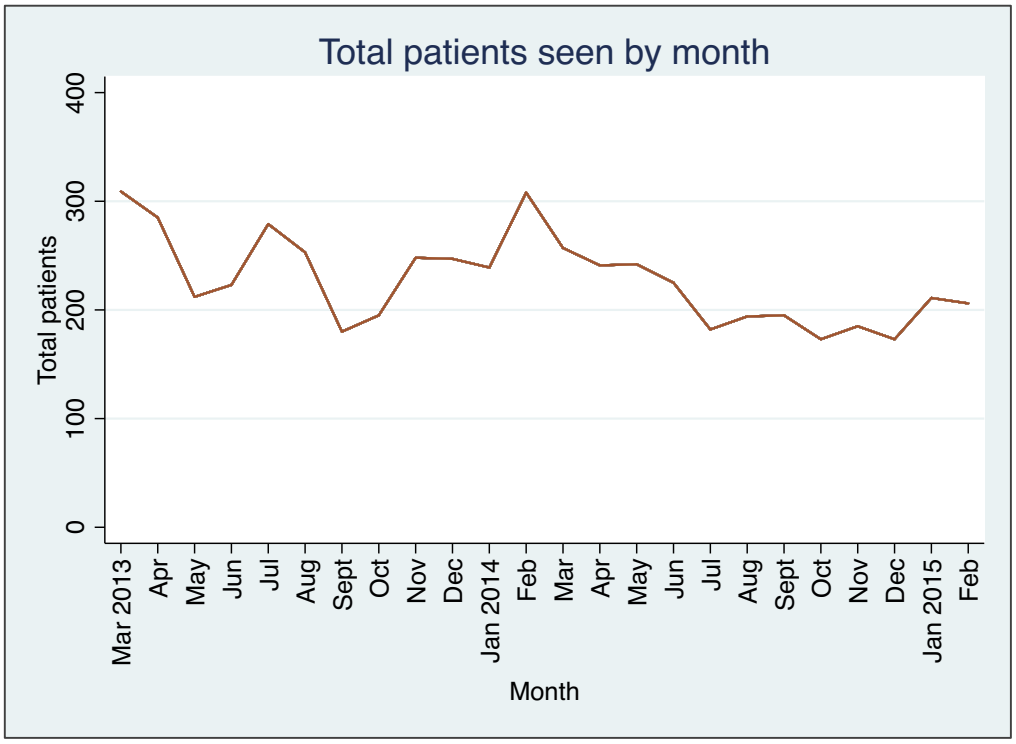


**Figure 9. Total positive RDTs by month**

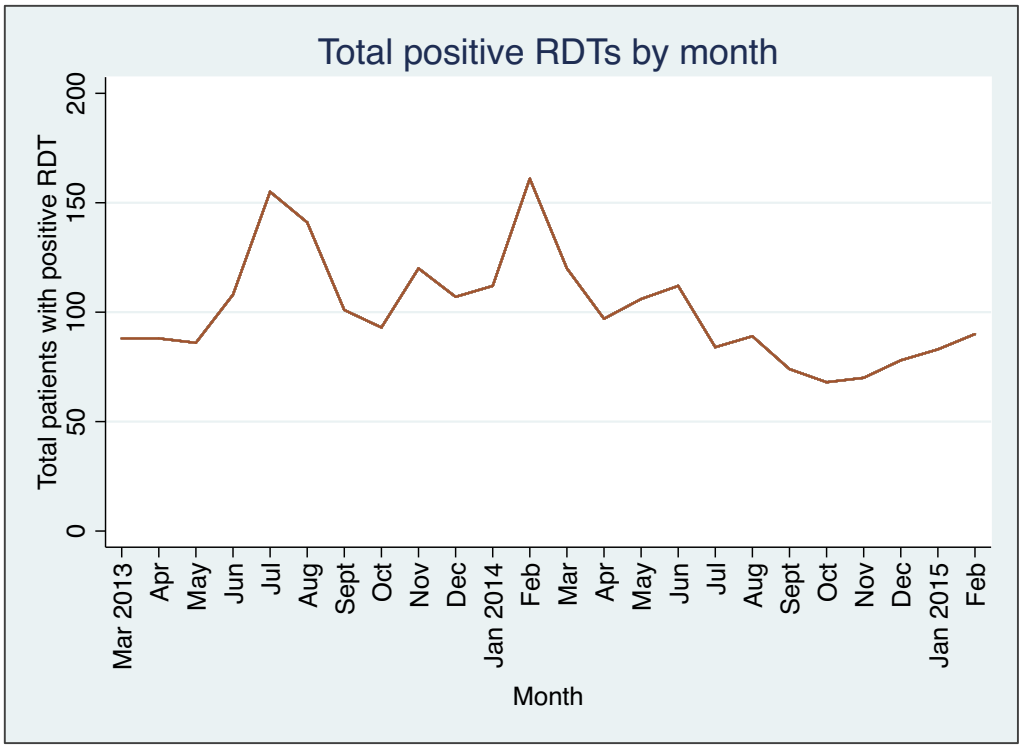
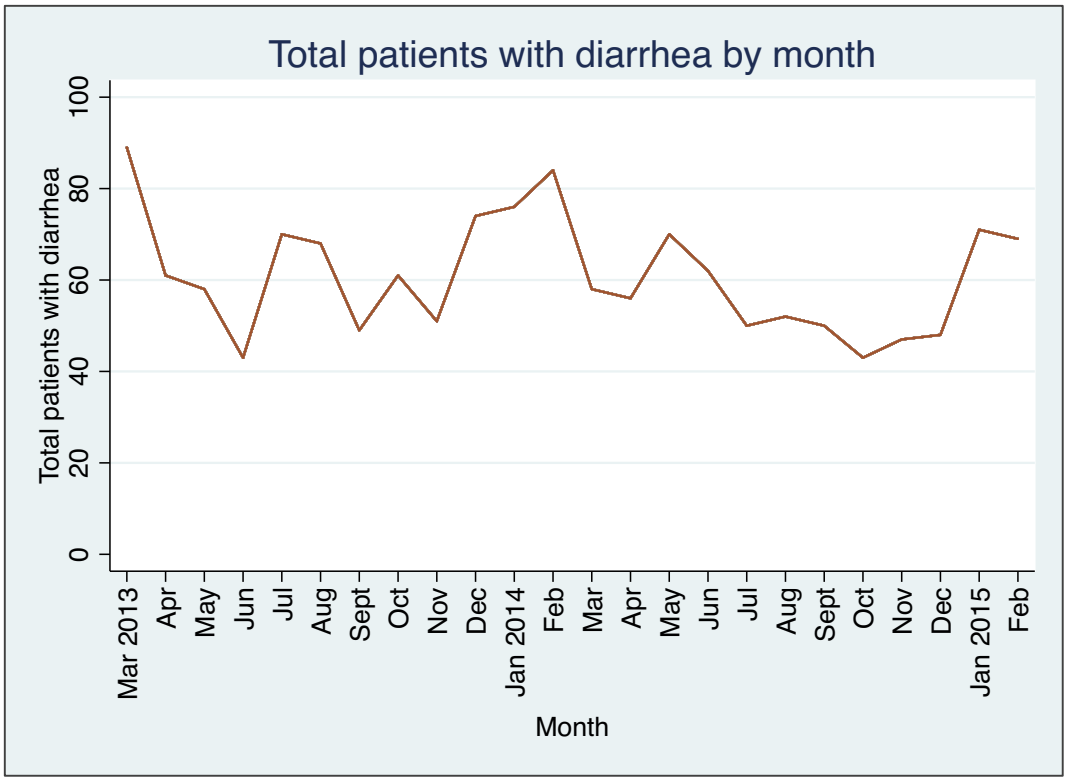



**Figure 10. Total diarrhea patients by month**



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